DOCKET NO.: CARP0057

PATENT

RESPONSE UNDER 37 CFR 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP NO. 1642

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#41/ne
KD
5-30-02

In re patent application of: **Adair et al.**

Serial No.: **08/846,658**

Group No.: **1642**

Filed: **May 1, 1997**

Examiner: **M. Davis**

For: **HUMANISED ANTIBODIES**

I, **Doreen Yatko Trujillo, Registration No. 35,719** certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Box AF, Assistant Commissioner for Patents, Washington, D.C. 20231.

On May 20, 2002

Doreen Yatko Trujillo

Doreen Yatko Trujillo, Reg. No. 35,719

Please date as May 20/02

BOX AF
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

REQUEST FOR RECONSIDERATION

Pursuant to 37 C.F.R. § 1.116, Applicants request reconsideration and withdrawal of the sole remaining rejection in this application. A Final Rejection was issued December 18, 2001. A petition for a two-month extension of time, and the appropriate fee, accompany this request.

Claims 24-31 are pending. Claims 24-31 were again rejected as allegedly unpatentable under under 35 U.S.C. § 102(e) in view of U.S. Pat. No. 5,585,089 (the "Queen patent"). Applicants respectfully traverse the rejection.

Preliminarily, Applicants thank the Examiner and her Supervisor for the very helpful interview conducted on January 31, 2002. During that interview, the rejection of claims 24-31 under 35 U.S.C. § 102(e) in view of the Queen patent was discussed. As Applicants stated during the interview, the Queen patent is not entitled to its earliest priority dates. Thus, it is not an appropriate reference under 35 U.S.C. § 102(e).

To recapitulate, the Queen patent claims priority to four earlier applications, two of which are continuations-in-part. For the Queen patent to be entitled to the earliest priority dates as a reference under 35 U.S.C. § 102(e), there must be support for the claims *as allowed* in those priority applications, i.e., the claims must comply with 35 U.S.C. § 112 as of those earlier filing dates, including the written description requirement. (See MPEP 2136.03, p. 2100-85, citing *In re Wertheim*, 209 USPQ 554 (CCPA 1981).) Applicants have maintained that several of the limitations recited in the claims as allowed in the Queen patent do not find written descriptive support in at least the two earliest Queen priority applications – i.e., Queen priority Application Serial No. 07/290,975, filed **December 28, 1988** ("Queen '975") and Queen priority Application Serial No. 08/310,252, filed **February 13, 1989** ("Queen '252"). If the claim limitations do not find written descriptive support in those earlier applications, then the Queen patent is not an effective reference under 35 U.S.C. §102(e) because Applicants are entitled to their GB priority date of **December 21, 1989,** which is earlier.

The limitation specifically focused upon during the aforementioned interview was the recitation "outside the Kabat and Chothia CDRs." This limitation is particularly significant because it was required for the Queen patent claims to be allowed. Indeed, it was argued that the claims distinguish over the prior art because the immunoglobulins contain donor amino acids "outside the Kabat and Chothia CDRs." (See Amendment dated May 31, 1996, page 5, of the application which issued as the Queen patent.) Neither the limitation, nor support therefor, however, was present in the claims or applications as originally filed in Queen '975 nor in Queen '252. Indeed, the claims as originally filed referred merely to "CDRs." It is Applicants' position that the patentees did not show possession of the later-claimed invention as of the filing dates of Queen '975 and Queen '252. The Queen patent, thus, is not entitled to those earlier filing dates

under 35 U.S.C. § 102(e).

In the Final Rejection, the Examiner again relied upon a single passage in Queen '975 (Queen '975 was incorporated by reference in Queen '252) to support the position that one of ordinary skill in the art would have recognized that CDRs as taught by Queen would also include CDRs as defined by Chothia et al, "regardless of whether the rest of the specification discloses as examples Kabat's CDR's." (*See* Final Rejection dated December 18, 2001, page 4.) As stressed during the interview, however, the Examiner's position is contrary to what was argued by the patentees themselves during prosecution of the European equivalents of the Queen patent when faced with rejections/objections similar to the written description requirement of 35 U.S.C. § 112, first paragraph. Notably, the European equivalents claim priority to Queen '975 and Queen '252.

In Queen's European patent 0 451 216 B1 ("the European patent," Exhibit 1), granted claim 1 recited that there was to be "at least one amino acid substitution outside of" CDRs "as defined by Kabat et al . . .together with Chothia et al . . ." The European patent was revoked in its entirety under Article 123(2) of the European Patent Convention, which is duplicated below:

> A European patent application or a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.

The European Board of Opposition ("European Board") concluded that

> the feature *Kabat [...]together with Chothia [...]"* in claim 1 has neither a technically reasonable nor a legal basis in the application documents as filed; claim 1 does not therefore meet the requirements of Art. 123(2) EPC.

(See Interlocutory decision in Opposition Proceedings, page 27, Exhibit 4.).[1] The European Board

[1] Like the written description requirement of 35 U.S.C. § 112, first paragraph, implicit support for amendments is also recognized under Art. 123(2) EPC. (See Decision T 0292/85, page 5, and Decision T 1212/97, page 6, Exhibits 2 and 3, respectively.) Clearly, then, the European Board did not find even implicit support for the feature.

interpreted the reference simply to "CDRs" in granted claim 7 without further definition to mean Kabat and Chothia CDRs and, thus, revoked it as well.

In an appeal of the decision revoking the patent, the patentees submitted claims similar to granted claim 7, i.e., referencing simply "CDRs." They argued that, contrary to the finding of the European Board,

> . . . unless specifically defining CDR's otherwise as done in granted claim 1, the person skilled in the art when reading the application as filed and the patent specification would have inevitably understood that the CDRs in granted claim 7 referred to Kabat CDRs.

(*See* paper filed June 22, 2001 by Protein Design Labs in appeal of EP 0 451 216 B1, page 8, Exhibit 5.) The Examiner's position, thus, is inapposite to the patentee's.

Indeed, in a paper filed in the opposition of a divisional patent stemming from the application that issued as the European patent, the patentees further argued that

> . . . the skilled person who turned to the experimental example in the contested Patent for guidance in carrying out the method of claim 1 would necessarily interpret CDRs according to the definition of Kabat.

(*See* paper filed July 13, 2001 by Protein Design Labs in EP 0 682 040 B1, page 7, Exhibit 6.) The patentees went so far as to state that

> . . . **nowhere** does the contested Patent state that the Chothia definition is to be used in **carrying** out the invention or in **understanding** the claims.

(*Id.*, page 6, emphasis added.) Claim 1 in the divisional patent recites, simply, "CDRs" (European patent 0 682 040 B1, Exhibit 7).

In view of the foregoing, Applicants respectfully submit that the Examiner's position regarding how one skilled in the art would interpret CDRs in Queen '975 and Queen '252 is not only inconsistent with the specification and contrary to the findings of the European Board,

but it is also contrary to what the patentees themselves argued to overcome revocation in Europe. Patentees should not be afforded one interpretation of the same claim limitation to avoid the prior art in the U.S. (i.e., CDRs mean Kabat plus Chothia), and another interpretation of the same claim limitation to meet, effectively, the written description requirement in Europe (i.e., CDRs mean Kabat only). The analysis in both forums on this point, i.e., written description, is essentially the same. Accordingly, Applicants respectfully request that the rejection of claims 24-31 be withdrawn and an interference between the present application and the Queen patent be declared. The Examiner is requested to contact the undersigned at (215) 564-8352 if she feels a telephonic discussion will be helpful.

Respectfully submitted,

Doreen Yatko Trujillo
Registration No. 35,719

Date: May 20, 2002

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100 - Telephone
(215) 568-3439 - Facsimile